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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,567	07/20/2001	Roberto A. Macina	DEX-0214	4354

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EXAMINER	
SMITH, CAROLYN L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 05/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/909,567	MACINA ET AL.	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/9/04 and 3/29/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Sequence Match Listing (2 pages).

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/9/04 has been entered.

The information disclosure statements, filed 3/9/04 and 3/29/04, have been fully considered by the Examiner.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1, as written, does not sufficiently distinguish over nucleic acids as they exist naturally because the claim does not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. It is noted on page 21, lines 33-34 of the specification, that "a variant of a polynucleotide may be a naturally occurring variant such as a naturally occurring allelic variant" which is clearly non-statutory subject matter. In the absence of the hands of man, the naturally occurring products are

considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980).

Claim Rejections – 35 U.S.C. 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

LACK OF WRITTEN DESCRIPTION

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time of the invention was filed, had possession of the claimed invention.

The specification discloses SEQ ID NO: 12 that corresponds to the nucleic acid sequence of a lung specific molecule. SEQ ID NO: 12 and its full complement meet the written description provisions of 35 U.S.C. 112, first paragraph. However, claim 1 is directed to encompass a variant polynucleotide that does not meet the written description provision of 35 U.S.C. 112, first paragraph. Due to the claim wording "comprising" on lines 3 and 5 of claim 1, this claim is directed to sequences that do not meet the written description provision of 35 U.S.C. 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by these claims.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry,

whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 12, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmacentical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only SEQ ID NO: 12 but not the full breadth of the claim 1 meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Applicants cite MPEP § 2163 (page 2100-165 to 2100-166) states that applicant may show an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that the applicant was in possession of the claimed

invention including partial structure. Applicants further state the instant specification teaches the 1823 nucleotide sequence of SEQ ID NO: 12 which meets the written description requirements for a claim drawn to a polynucleotide comprising this sequence. This is found unpersuasive as only SEQ ID NO: 12 and its full-length complement have adequate written description. The specification on pages 18-22 describes various instances of the term "variant" as stated in the instant claim. On page 18, lines 18-23 and 27-30 of the instant specification, the changes in the nucleotide sequence of the variant may alter the amino acid sequence by one or more substitutions, additions, deletions, and fusions which result in different sequences with possibly different functions. The phrase "polynucleotide encoding a polypeptide" is defined on page 21, second paragraph, as encompassing regions including introns together with additional regions that may also contain coding and/or non-coding sequences. These additional regions were not specifically described by applicants that would alter the sequence and possibly its function. This alteration that may produce conservative or non-conservative amino acid substitutions, deletions, or additions, is stated on page 22, second paragraph, of the specification. Applicants have not described and provided details on these additional sequences to verify that applicants were in possession of these types of sequences at the time of the invention which therefore results in a lack of written description. Applicants arguments regarding % identity are rendered moot due to the deletion of this subject matter from the instant invention. Applicants cite MPEP § 2163 (page 2100-169) which states if an applicant discloses an amino acid sequence that it is unnecessary to provide an explicit disclosure of nucleic acid sequence encoding the amino acid sequence. This is found unpersuasive as it was previously noted in earlier prosecution that the amino acid sequence encoded by a nucleic acid of SEQ ID NO: 12 was not explicitly provided. SEQ ID NO: 48, the closest amino acid sequence resembling an amino acid sequence encoded by SEQ ID NO: 12 is not actually encoded by SEQ ID NO: 12 which has an extra cytosine at

position 71. Therefore, applicants' arguments regarding MPEP § 2163 (page 2100-169) are considered unpersuasive.

Claims Rejected Under 35 U.S.C. § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claim 1, line 6, recites the phrase "variant" which is vague and indefinite due to the unclarity of the term. The claim does not adequately define the phrase which could mean a variant which is 5% different and of the same length as the claimed polynucleotide or 20% different and only a fragment of the sequence or any other scenario. The specification on pages 18 to 22 provide various examples and alternatives of possible variants, but no clear definition of how it should be defined in instant claim 1. Clarification of the metes and bounds of the claim regarding the degree of variation to the claimed polynucleotide is required.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claim 1 of this application. The claimed sequences were not disclosed in the provisional application, therefore the earliest effective filing date is 7/20/01 for the instant application.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Bandman et al. (P/N 6203979). The term "variant" has been amended back into the instant invention's claim language such that Bandman et al. reference is once again applied as prior art upon reconsideration. As the term "variant" is broadly defined on page 18 of the specification (regarding the degree of variation in nucleotides and sequence length), Bandman et al. disclose a sequence from a lung (SEQ ID NO: 16, see attached Sequence Match Listing) which contains an identical matching polynucleotide sequence (nucleotide positions 80-705) to a fragment of instant SEQ ID NO: 12 (nucleotide positions 612-1237) which represents a variant polynucleotide encoding the polypeptide of (b), as stated in instant claim 1.

Thus, Bandman et al. anticipates instant claim 1.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al. (WO 99/60160). As the term "variant" is broadly defined on page 18 of the specification (regarding the degree of variation in nucleotides and sequence length), Yang et al. disclose a lung specific gene (AAZ29722, SEQ ID NO: 3, see attached Sequence Match Listing) which contains an identical matching polynucleotide sequence (nucleotide positions 80-705) to a fragment of instant SEQ ID NO: 12 (nucleotide positions 612-1237) which represents a variant polynucleotide encoding the polypeptide of (b), as stated in instant claim 1.
Thus, Yang et al. anticipates instant claim 1.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

April 27, 2004

Ardin H. Marschel 5/11/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER